



PEDIATRIC BLOOD AND MARROW TRANSPLANT PROGRAM

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DOCUMENT TITLE:

Infusion of Thawed Autologous and Allogeneic Cord Blood Cells or hCT-MSCs for Patients Receiving Cellular Therapy

DOCUMENT NOTES:

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PBMT-GEN-060

INFUSION OF THAWED AUTOLOGOUS AND ALLOGENEIC CORD BLOOD CELLS OR hCT-MSCs FOR PATIENTS RECEIVING CELLULAR THERAPY

1 PURPOSE

- 1.1 To outline the procedure for the infusion of thawed autologous or allogeneic cord blood cells in patients receiving cellular therapy. The cord blood cryopreserved products have been shipped to the Duke Stem Cell Transplant Laboratory (STCL), completed confirmatory typing and potency testing, and thawed and washed for removal of DMSO (dimethyl sulfoxide) and volume reduction. The human cord tissue mesenchymal stromal cells (hCT-MSCs) have been manufactured by the Robertson GMP Laboratory and delivered to the STCL. After processing and configuration for reinfusion, the products are transported to the patient's bedside for infusion.

2 INTRODUCTION

- 2.1 On the day of infusion or transplantation, cryopreserved autologous or allogeneic umbilical cord blood cells or hCT-MSCs are prepared for infusion in the SCTL.
 - 2.1.1 The clinical team confirms that the infusion will occur and provides the weight of the patient to the SCTL within a few days of the scheduled infusion.
- 2.2 Umbilical cord blood (UCB) cells may be prepared for administration in a syringe or a bag. If prepared in a bag, an infusion set (blood administration tubing) will be used for administration.
- 2.3 If provided in a syringe, the syringe is attached to stopcock and the tubing is primed with the product by the STCL. hCT-MSCs are provided in a syringe and the syringe is attached to the stopcock and tubing is primed with the product by the STCL.
- 2.4 The patient is pre-medicated 5-120 minutes prior to administration of the cells to prevent infusion-related reactions. In addition to pre-medications, it is required to have emergency-use medications available at the bedside.

3 SCOPE AND RESPONSIBILITIES

- 3.1 The Laboratory Manager, Program Medical Director, Nurse Manager, Attending Physician on service, the care nurse, and/or the clinical study team are responsible for ensuring the requirements of this procedure are successfully met.

4 DEFINITIONS/ACRONYMS

- 4.1 ABMT Adult Blood and Marrow Transplant
- 4.2 CHC Children's Health Center
- 4.3 DMSO Dimethyl Sulfoxide

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- 4.4 EMR Electronic Medical Record
- 4.5 hCT-MSC Human Cord Tissue Mesenchymal Stromal Cells
- 4.6 IV Intravenous
- 4.7 PPE Personal Protective Equipment
- 4.8 RN Registered Nurse
- 4.9 STCL Stem Cell Transplant Lab
- 4.10 UCB Umbilical Cord Blood
- 4.11 VDH Valvano Day Hospital

5 MATERIALS

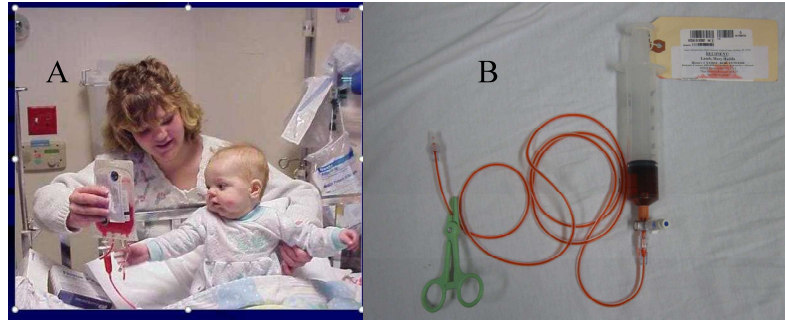
- 5.1 Transplant bag (provided from STCL)
- 5.2 Normal Saline attachment in satellite bag
- 5.3 Y-Type blood/solution set with standard blood filter (170-260 micron filter)
- 5.4 BD 10 luer-lock syringe
- 5.5 3-way stopcock
- 5.6 Three (5 mL) normal saline syringes
- 5.7 A needle-less blue port - attached to both the proximal and distal stopcocks on the primed cell product tubing
 - 5.7.1 STCL adds the proximal port
 - 5.7.2 nursing will add the distal port if not already placed by STCL
- 5.8 Tape
- 5.9 Mask
- 5.10 IV (intravenous) start kit
- 5.11 Tourniquet
- 5.12 Sterile gloves
- 5.13 Alcohol preps (10)
- 5.14 2X2 gauze (4)
- 5.15 4X4 gauze (2)
- 5.16 Bandaid
- 5.17 Tegaderm
- 5.18 Two each of 22 gauge (1") or 24 gauge (3/4") angiocath needles;
 - 5.18.1 a 24 gauge (1/2") can be used for small babies
- 5.19 IV Fluids – D5 ½ NS (or age appropriate fluid as ordered by physician or designee)

5.20 STCL-SOP-050 *Infusion Form*

5.21 Accompanying paperwork

5.22 Specimen Requirements:

Thawed, appropriately labeled, transplant product either (A) in a bag or (B) in a syringe with a stopcock and primed tubing.



6 EQUIPMENT

6.1 IV Syringe Pump

7 SAFETY

7.1 Appropriate Personal Protective Equipment (PPE) must be worn when handling cellular therapy products.

8 PROCEDURE

8.1 The patient will arrive to McGovern-Davison Children's Health Center (CHC) for check-in at the front desk. Note: Infusions can also take place as an inpatient or in the ABMT (Adult Blood and Marrow Transplant) clinic and check-in procedures will correspond with location.

8.1.1 Every effort will be made to obtain patient weight, height, and vital signs according to hospital policy.

8.1.2 The patient armband will be placed by on the recipient. The registered nurse (RN) will verify the recipient's armband by asking parent the child's name and date of birth just prior to administration of any medications.

8.2 The nurse practitioner or physician will write premedication orders, emergency medication orders, and post IV hydration orders in the electronic medical record (EMR).

8.3 The cellular therapy product will arrive to the patient care unit and will be accepted by either a Valvano Day Hospital (VDH) assigned RN (or corresponding location care nurse if product is being infused in an alternate location) or one of the study staff.

- 8.4 Two licensed medical personnel will verify the product to be infused by double-checking the paperwork to the product. Then, a “time out” is performed by the infusion team at the patient’s bedside-
 - 8.4.1 The licensed medical personnel can consist of the following roles: registered nurse, nurse practitioner, and/or physician.
- 8.5 Two licensed medical personnel will then verify the product to the patient’s armband and confirm that the patient has received the prescribed pre-medications prior to initiating the infusion.
- 8.6 Apply the probe to the patient to monitor heart rate, oxygen (O₂) saturations and blood pressure as tolerated during the infusion.
- 8.7 Product Preparation:
 - 8.7.1 If the product is in a bag- the licensed medical personnel will prepare the product using the Y-Site Blood tubing, first roller clamp one of the two double spikes and roller clamp the primary line of the blood tubing. (Do not tie a knot in one end of the double spikes.) The licensed medical personnel will spike the product with the blood set.
 - 8.7.2 If the product is in a syringe, place the 60 mL syringe containing the product into the Syringe Pump. A smaller syringe may be utilized if the product will be a smaller volume (i.e. 5 mL). Syringe size will be at the discretion of the STCL. The Alaris syringe pump is illustrated in the picture below:



- 8.8 Pre-Medications:
 - 8.8.1 A registered nurse or other trained team member will start an IV, if required, and administer the prescribed IV medications.
 - 8.8.2 Diphenhydramine and methylprednisolone are utilized to prevent infusion-related reactions.

- 8.8.3 Alternate medications may be substituted at the discretion of the covering provider if medically indicated (i.e. allergy) or via an alternate route as clinically suitable.
- 8.9 Emergency Supplies:
 - 8.9.1 Emergency medications, most commonly diphenhydramine, methylprednisolone, albuterol and epinephrine will be supplied from pharmacy and will remain at the bedside during the infusion.
 - 8.9.2 Emergency equipment, including but is not limited to an appropriately sized ambu bag, oxygen tubing, nasal cannula, nebulizer tubing, 1 mL syringe, 25 g needle, 3 mL syringe, and saline flushes, must be available prior to the start of the product infusion and remain available until the patient is cleared to leave the patient care unit.
- 8.10 Product Infusion:
 - 8.10.1 The cellular product tubing will be connected to peripheral intravenous tubing with the needleless port removed. The cord blood cells will be infused over 5 to 30 minutes. hCT-MSCs will be infused over 30 to 60 minutes. Attention will be paid to the expiration time to ensure the product is infused before expiration. If it appears the product may not be completely infused prior to expiration, the team must discuss with the physician covering the infusion and the physician must document their approval to proceed or continue.
 - 8.10.2 If the product is in a bag, the IV fluids will be connected to the patient's IV with the needleless port removed and infused at the ordered rate.
 - 8.10.3 If the product is in a syringe, the IV fluids will be connected to the stopcock on the syringe. After infusing the cells from the syringe, turn the stopcock off to the syringe and infuse the IV fluids at the ordered rate.
- 8.11 Monitoring and Documentation:
 - 8.11.1 The RN (study team or care nurse) will obtain and record vital signs every 2-5 minutes for 15 minutes or until the infusion is complete. The patient will be observed for a minimum of one-hour post infusion.
 - 8.11.2 The RN (study team or care nurse) will document the infusion on the SCTL-SOP-050 *Infusion Form*.
 - 8.11.3 The study team RN will follow up with the patient either in person or via a phone call to evaluate patient clinical status 24 hours post infusion. Documentation of any adverse events will be completed on the STCL-SOP-050 *Infusion Form*, in the EMR, (and in RedCap, if applicable). The patient will be triaged accordingly.
 - 8.11.4 The RN (study nurse or care nurse) will document the following in the EMR:

- 8.11.4.1 Heart rate
- 8.11.4.2 Oxygen saturations
- 8.11.4.3 Medication administration Times
- 8.11.4.4 Information for the cord blood infusion (Stem Cell Infusion Data tab).
- 8.11.5 The NP or physician will document the infusion in the EMR.
- 8.11.6 The RN (study team or care nurse) will document any adverse experiences during the infusion or within the 24 hour time period following the infusion on form STCL-SOP-050 *Infusion Form*. Once documentation on STCL-SOP-050 *Infusion Form* is complete, the nurse will provide a copy of the form to the SCTL for inclusion in the patients STCL file.
- 8.11.7 Post infusion follow-up evaluations will be completed via questionnaire and/or via a follow-up phone call, as applicable per individual study protocols.
- 8.11.8 Maintain documents per hospital policy.

9 RELATED DOCUMENTS/FORMS

- 9.1 STCL-SOP-050 Infusion Form

10 REFERENCE

- 10.1 Buchsel, PC and PM Kapustay, Eds. Stem Cell Transplantation: A Clinical Textbook. Oncology Nursing Press, Pittsburgh PA. 2000.

11 REVISION HISTORY

Revision No.	Author	Description of Change(s)
07	S. McCollum/	<ul style="list-style-type: none"> - Section 2.4 updated to expand timeframe for premeds - Materials Section: Needless Blue port added - Materials section: angiocath needles updated - Section 8.4: insertion of time out language - Section 8.8: Inserted “or other trained team member” for IV start - Section 8.11.4: Nursing documentation updated

Signature Manifest**Document Number:** PBMT-GEN-060**Revision:** 07**Title:** Infusion of Thawed Autologous and Allogeneic Cord Blood Cells or hCT-MSCs for Patients Receiving Cellular Therapy**Effective Date:** 21 Oct 2021

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